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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/568,633

10/26/2006

Gerrit Dirk Keizer

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LADAS & PARRY LLP
26 WEST 61ST STREET
NEW YORK, NY 10023

EXAMINER

CHIN, CHRISTOPHER L

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/568,633	Applicant(s) KEIZER ET AL.	
	Examiner Christopher L. Chin	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 February 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1/26/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Priority

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Claim Rejections - 35 USC § 112

2. Claims 1-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague. Line 3 appears to recite a trademark compound – Barnox. Generic terminology should be inserted to define the trademark compound since the composition of a trademark compound is subject to change while its name can stay the same. Line 3 also recites the acronyms PVC, EVA, and PET. Generic terminology should also be used to define these acronyms to clearly define these materials.

Claim 3 is vague because it recites the acronym PVDF. Generic terminology should also be used to define these acronyms to clearly define these materials.

Claims 8 and 12 are vague for reciting the abbreviation/acronym BSE and TSE, respectively.

Claim 10 is vague. In step (c), the phrase "in said containers bar performing" is not clear. Step (c) is also vague because it recites detection with a chemiluminescent immunoassay but no chemiluminescent reagents are recited in the claim. Step (b) is

also not clear because the step recites a filtering step using the membrane filter but the plate of claim 1 fails to recite the bottom of the wells being open to let filtrate leave the wells after going through the membrane filter in each well.

3. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 2 recites the broad recitation "preferably an integer from 2-10", and the claim also recites "more preferably 2-5" which is the narrower statement of the range/limitation.

4. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent

protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 12 recites the broad recitation prion, and the claim also recites "preferably a TSE-causing prion" which is the narrower statement of the range/limitation.

5. Claims 13 and 14 provides for the use of a microtiter plate, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 13-14 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Glezer et al in view of Coleman et al.

Glezer et al (PGPub US 2003/0113713 A1) discloses a microplate device wherein groups of wells are segregated (see Fig. 10A). Each of the wells contain electrodes and reagents for performing electrochemiluminescence (ECL) assays to detect one or more analytes in a sample [0006-0007]. Various types of analytes can be detected in the disclosed microplate [0058-0059]. The electrodes can be composed of carbon fibrils or carbon nanotubes dispersed in a polymeric matrix. The electrodes can be supported on paper, meshes, felts, or fibrous materials [0098-0100]. The electrodes support analyte specific binding reagents [0106-0111].

The fibrous electrodes read on the permeable membrane filter of the instant invention since they are permeable membranes, fibrous to function as a filter, and support analyte specific binding reagents.

While the microplate of Glezer et al shows that groups of wells are separated from other groups of wells, there is no "cluster dividing wall" that separates each group of wells where the "cluster dividing wall" is of a greater height than the walls of the wells.

Coleman et al (US Patent 5,441,894) disclose a multiwell assay device where dividing wall (26) with a height greater than the walls of the wells separates each of the wells from each other (see Figure 1). The dividing wall (26) acts as a light seal when a chemiluminescence detector, with matching groove padded with compressible polymeric material, mates with it (col. 5, lines 47-59).

It would have been obvious to one of ordinary skill in the art to surround each of the groups of wells in the microplate of Glezer et al with a dividing wall like that taught by Coleman et al because the dividing wall would prevent sample spillover contamination from the other groups of wells and also provide a light seal when the ECL reactions are read in each of the wells with the appropriate chemiluminescence detector.

With respect to claim 3, PVDF is a well known material for making filter membranes and thus would be an obvious material for use to support the electrodes in the wells of Glezer et al.

With respect to claims 8, 9, and 12, Glezer et al teaches the detection of a wide variety of analytes given the appropriate corresponding analyte binding reagent. The choice of analyte binding reagent for use in the microplate of Glezer et al is dictated by the analyte that is to be detected. It would be obvious to one of ordinary skill in the art to

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use the appropriate binding reagent for detection of the specific analytes recited in claims 8, 9, and 12.

Conclusion

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

The following patents and PGPub disclose multiwell devices:

4,077,845 4,948,564 5,948,363

4,111,754 5,108,704 6,315,940

4,294,931 5,110,556 6,830,239

4,545,958 5,227,290 US 2002/0164812 A1

4,895,706 5,326,533

4,948,442 5,417,923

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher L. Chin whose telephone number is (571) 272-0815. The examiner can normally be reached on Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Christopher L. Chin/
Primary Examiner, Art Unit 1641

6/16/08